

I. CLAIM LISTING

- 1 (Withdrawn) A method for obtaining antigen-specific antibodies to a target bacterial carbohydrate antigen selected from among lipo-polycarbohydrate antigens, antigens comprising lipoteichoic acids or teichoic acid or derivatives of either, and capsular carbohydrate antigens, which comprises the step of:
- (a) purifying the target bacterial carbohydrate antigen to produce essentially protein-free antigen containing not more than about 10 percent of protein by weight,
 - (b) coupling said essentially protein-free antigen to a spacer molecule to produce a conjugate,
 - (c) coupling the conjugate from step (b) to an affinity gel to produce a further conjugate,
 - (d) passing raw polyclonal antibodies to the target bacterial antigen or an IgG cut thereof, over the further conjugate of step (c), and
 - (e) eluting from the further conjugate of step (c) purified antibodies specific to the crude target bacteria antigen.
- 2 (Withdrawn) Antigen-specific antibodies prepared by the method of Claim 1.
- 3-22 (Cancelled)
- 23 (Amended) The method of claim [[22]] 53 in which the species, or serogroup of a species, of bacteria in step (a) are gram-negative bacteria and the crude target carbohydrate antigen component thereof sought to be detected in step (d) is a

lipopolysaccharide.

- 24 (Amended) The method of claim [[22]] 53 in which the species, or serogroup of a species, of bacteria in step (a) are gram positive bacteria and the crude target carbohydrate antigen component thereof sought to be detected in step (d) is a lipoteichoic acid, a teichoic acid, or a derivative of either.
- 25 (Amended) The method of claim [[22]] 53 in which the species, or serogroup of a species, of bacteria in step (a) are either gram-negative or gram-positive bacteria and the target carbohydrate antigen component thereof sought to be detected in step (d) is a capsular polysaccharide antigen.
- 26-27 (Cancelled)
- 28 (Amended) the method of claim [[22]] 53 wherein the liquid sample of step (d) is a natural fluid of mammalian origin.
- 29 (Previously presented) The method of claim 28 wherein the liquid sample of step (d) is human urine.
- 30 (Amended) The method of claim 28 wherein the liquid sample of step (d) is obtained from a human patient exhibiting clinical signs of a disease known to be caused by the selected species, or selected serogroup of a species, of bacteria referred to in step (a).
- 31 (Amended) The method of claim [[22]] 53 in which step (d) is an immunoassay process.
- 32 (Previously presented) The method of claim 31 in which step (d) is an immunochromatographic ("ICT") process.

- 33 (Amended) The method of claim 32 in which the bacteria referred to in step (a) are *Haemophilus influenzae* type b bacteria and the crude target carbohydrate antigen sought to be detected in step (d) is the capsular carbohydrate antigen of those bacteria.
- 34 (Cancelled)
- 35 (Amended) The method of claim [[34]] 54 in which the bacteria are gram-positive gram-negative bacteria and the characteristic crude target carbohydrate antigen sought to be detected is a lipopolycarbohydrate antigen.
- 36 (Amended) The method of claim [[34]] 54 in which the bacteria are gram-negative gram-positive bacteria and the characteristic crude target carbohydrate antigen sought to be detected is a lipoteichoic acid, a teichoic acid, or a derivative of either.
- 37 (Amended) The method of claim [[34]] 54 in which the bacteria are gram-positive or gram-negative bacteria and the characteristic crude target carbohydrate antigen sought to be detected is a capsular carbohydrate antigen.
- 38 (Amended) The method claim [[34]] 54 in which the liquid sample is a natural fluid of mammalian origin.
- 39 (Previously presented) The method of claim 38 in which the liquid sample is human urine.
- 40 (Amended) The method of claim 39 in which the liquid sample is obtained from a human patient exhibiting symptoms of a disease known to be caused by the species, or serogroup of a species, of bacteria of which the crude target carbohydrate antigen is known to be characteristic. ~~that was cultured in step (a) of claim 22.~~

41. (Amended) The method of claim [[34]] 54 in which the labelling agent is finely divided gold.

42 (Amended) The method of claim 39 in which the crude target carbohydrate antigen sought to be detected is the capsular carbohydrate antigen of *Haemophilus influenzae* type b.

43-52 (Cancelled)

53 (New) A method for detecting the presence in a fluid sample of a target carbohydrate antigen characteristic of a selected species, or a selected serogroup of a species, of bacteria which comprises the following steps:

- D 1
- (a) obtaining from a culture of the selected species, or selected serogroup of a species, of bacteria an embodiment of said target carbohydrate antigen that is essentially protein-free,
 - (b) coupling said essentially protein-free embodiment of said target carbohydrate antigen from step (a) to a chromatographic affinity gel,
 - (c) passing polyclonal antibodies raised in a mammal against said bacteria or said target carbohydrate antigen in crude form, over the chromatographic affinity gel obtained in step (b) and eluting there from antibodies with enhanced specificity to the said target carbohydrate antigen, and

(d) conducting an assay upon a liquid sample suspected of containing the crude target carbohydrate antigen, which assay comprises the steps of

(I) contacting the liquid sample with a detection agent comprising antibodies with enhanced specificity to said target carbohydrate antigen obtained in step (c) hereof, at least a portion of which have been labelled with a labelling agent known to manifest a detectable characteristic upon the formation of a reaction product between said antibodies and said crude target carbohydrate antigen and

(ii) detecting the presence in the sample, when present, of said crude target carbohydrate antigen by observing the manifestation of said detectable characteristic therein

54 (New) The method of Claim 53 in which step (d) comprises an ICT assay conducted in an ICT device comprising a strip of bibulous material disposed laterally within a housing, which housing is equipped with a view window and wherein said strip of bibulous material comprises at least (1) a first zone in which is deposited, at a location near the sample receiving end of the strip a moveable deposit of antibodies obtained in step (c) of Claim 53 having enhanced specificity to said target carbohydrate antigen, which antibodies have been labelled prior to being so deposited with a labelling agent selected from among those labelling agents which display a visible color change upon the formation of a labelled antibody-antigen-immovable antibody reaction product, and

(2) a second zone so positioned that it is near the opposite end of said strip relative to the first zone and is observable through the view window in the housing of said ICT device, in which another portion of antibodies obtained in step (c) of Claim 53 have been immovably bound to said strip, and the ICT assay is carried out by

- (A) contacting said liquid sample with said strip at its sample receiving end,
- (B) allowing said sample to flow laterally into said first zone and pick up said moveable deposit of labelled antibodies that has been placed there,
- (C) allowing said sample and said conjugate to flow together laterally to said second zone while in intimate contact with one another, thereby enabling target carbohydrate antigen, if present in the sample, to react at least partially with said conjugate to form further labelled antibody-antigen conjugates,
- (D) allowing the laterally flowing stream from step (C) to flow into said second zone and contact said antibodies immovably bound to said strip and
- (E) within approximately 15 minutes from introduction of sample to the strip, observing through the window in the housing whether a line of color has formed, indicating the formation of a labelled antibody-antigen-immovable antibody reaction product and confirming the presence in the sample of the target carbohydrate antigen.

55 (New) As an article of manufacture, an ICT device comprising a housing equipped with a view window in which is laterally disposed a strip of bibulous material comprising at least

- 1) a sample receiving zone at one end of said strip,
- 2) a first zone positioned in the sample flow path near the sample receiving zone, in which zone has been pre-deposited a movable deposit of prelabelled antibodies, which antibodies have been obtained from step (c) of Claim 53 and are characterized by enhanced specificity to a target carbohydrate antigen known to be characteristic of a selected species, or a selected serogroup of a species, of bacteria, and have been labelled with a labelling agent selected from among those labelling agents which display a visible color upon the formation of a labelled antibody-antigen-immovable antibody reaction product, and
- 3) a second zone positioned so that it is observable through the view window of the housing of the device and is in the sample flow path close to the end of said strip that is opposite to the end where the sample receiving zone is located, in which zone a portion of unlabelled antibodies have been immovably bound to said strip, said antibodies having also been obtained from step (c) of Claim 53 and being characterized by enhanced specificity to the same target antigen known to be characteristic

1)

of the same selected species, or the same selected serogroup of a species,
of bacteria as the antibodies contained in the movable conjugate
deposited in said first zone.

56 (New) The ICT device of Claim 55 wherein the antibodies in the conjugate movably
deposited in said first zone and the identical antibodies immovably bound to the
strip in said second zone have enhanced sensitivity to a selected target
carbohydrate antigen known to be characteristic of a selected species, or a
selected serogroup of a species, of Gram-negative bacteria.

57 (New) The ICT device of Claim 55 wherein the antibodies in the conjugate movably
deposited in said first zone and the identical antibodies immovably bound to the
strip in said second zone have enhanced sensitivity to a selected target
carbohydrate antigen known to be characteristic of a selected species, or a
selected serogroup of a species, of gram-positive bacteria.

58 (New) The ICT device of Claim 55 wherein the antibodies in the conjugate movably
deposited in said first zone and the identical antibodies immovably bound to the
strip in said second zone have enhanced sensitivity to a selected target
carbohydrate antigen that is a capsular polycarbohydrate antigen characteristic
of a selected species, or a selected serogroup of a species, of either gram-
negative or gram-positive bacteria.

59 (New) An ICT device according to claim 55 wherein the antibodies in the conjugate movably deposited in said first zone and the identical antibodies immovably bound to the strip in said second zone are present in each zone in a concentration between 7.7 nanograms and 385 nanograms per square millimeter of surface area of said strip.

II. PRIORITY

The assertion in the Office action that “Appellant’s claim for domestic priority under 35 U.S.C. §119(e) is acknowledged” is not understood. Applicants have made *no such claim* under 35 U.S.C. §119(e) and have filed no “provisional” application--though a provisional application appears to be a prerequisite to a priority claim under the stated section. Applicants also are *not* seeking the filing date of any prior application as the priority date of this application.

What applicants *have* made is a claim for priority under 35 U.S.C. §120 for the subject matter disclosed in each of the prior, commonly assigned U.S. applications Ser Nos. 09/139,720, 09/156,486, 09/397,110 and 09/458,998. In *no* instance are Applicants claiming that any of these prior applications discloses the *entirety* of the invention of this application. What Applicants *are* claiming here is that each of the first three of these applications fully discloses a method that is within the scope of and a species of the generic methodology disclosed and claimed herein--and that this application is entitled *in part* to the priority dates of these three earlier applications--or, in other words, in each instance, to priority for the specific segment of this generic methodology that is therein disclosed and claimed. As to Ser. No. 09/458,998, which discloses a mode of use of purified antibodies within the scope of this application for detection in an enzyme immunoassay (“EIA”) rather than an ICT test of crude bacterial carbohydrate antigen in environmental water, that application thus illustrates that the purified antibodies are useful in other types of assays besides the rapid ICT test that is a part of the present generic invention. In other words, as the present application states, it is a

continuation-*in-part* of all the various prior applications identified because it embraces specific subject matter disclosed and claimed in each of them and it adds additional subject matter that they do not contain. This is consistent with the definition of a continuation-in-part application contained in each of 37 CFR 1.53(b)(2) and in MPEP. 201.08.

As noted in MPEP 201.08,

“Unless the filing date of the earlier nonprovisional application is actually needed, for example, in the case of an interference or to overcome a reference, there is no need for the Office to make a determination as to whether the requirement of 35 U.S.C. 120...is met.”

The paragraph goes on to state, in substance, that so long as (a) the earlier filed application has at least one inventor in common with this one, (b) this one was filed before the patenting or termination of proceedings on the earlier applications (or applications entitled to the benefit of the earlier applications) and (c) this one contains a specific reference to the earlier filed applications, there is no impediment to reliance *in part* on an earlier filed application. The logical conclusion is that this application is entitled to continue to claim the partial benefit of each of the identified earlier filed applications.

The Examiner *is correct* that this application describes and claims a generic concept--*an invention not disclosed* in any of the prior applications. That is why *only* the *partial* benefit of each prior application is or can be claimed herein. But it is nevertheless correct that the present applicants are *entitled* to claim the dates of the prior applications for the *more limited* subject matter, completely within the scope of this application, that each of the prior applications identified *does* disclose.

Because the relationships of each of the earlier-filed applications to this one can be viewed as a relationship of species to genus, the applicants herein are entitled to the individual benefits of each only *in part*--i.e., only in that part of each which is encompassed in what this application generically discloses and claims. To be more explicit, this application and its claims *may* rely (1) *in part* upon Ser. Nos. 09/139,720 alone for priority with respect to using the affinity purified antibodies within the scope of this invention for the detection in human bodily fluids of the O-polysaccharide antigen of *Legionella pneumophila*, serogroup 1; and (2) *in part* upon Serial No. 09/458,998 for priority with respect to using affinity-purified antibodies within the scope of the present invention for detection of O-carbohydrate antigens of *Legionella* bacteria by an enzymeimmunoassay method, rather than the ICT method covered by claims herein except claims for and (2) *in part* upon Ser. Nos. 09/156,486 and 09/397,110 for priority with respect to using the affinity purified antibodies within the scope of this invention for the detection in human bodily fluids of the cell wall carbohydrate antigen common to all serotypes of *Streptococcus pneumoniae* bacteria. Insofar as the overall generic concept is concerned, and/or the detection of carbohydrate antigens of any bacteria not involved in the earlier applications is called into question, this application is necessarily confined to its own filing date for priority purposes.

The Examiner's refusal in the Office Action of the limited partial priority of each of the prior applications, however, is totally contrary to 35 U.S.C. §120 as it has consistently been interpreted, both in the U.S. Patent and Trademark Office and in decisions of the courts for a time that antedates July 19, 1952 (when §120 of the Patent Act of 1952 was first formally codified into law) by many years. The Examiner is therefore courteously requested to

withdraw the denial of priority set forth in the action.